



Manufacturers of SPERTI Products

1057 '99 MAY 17 P1:26

May 12, 1999

Department of Health & human Services
Dockets Management Branch (HFZ-305)
Food & Drug Administration
5630 Fishers Lane, Room 1061
Rockville, Md. 20852

RE: 21CFR Part 1040, Docket No. 98N-1170

Sirs:

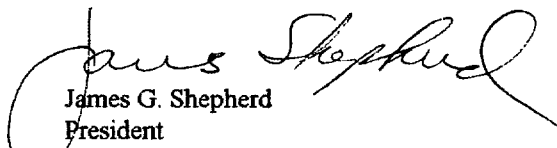
SPERTI Sunlamps is a small manufacturer of sunlamp products. These sunlamps are designed and provided for home facial tanning use and are sold primarily through catalogues. SPERTI has been manufacturing sunlamps for tanning since the 1930s. The SPERTI sunlamp is a filtered intermediate pressure mercury lamp. Unlike recent UVA/UVB lamps, this lamp primarily emits melanogenic UVB radiation wavelengths.

The primary change in the SPERTI tanning lamp has been the addition of a timer, modern UV protective goggles, and the inclusion of appropriate up-to-date warning information about potential dangers incurred by excessive UV exposure.

We are in agreement with the Agency that the timer and exposure schedule may require re-examination. Our exposure timer has been set to about 1/3 of the current Te value allowing only that exposure or less to be administered. As such our exposure schedule is less complicated than the schedule used for larger commercial tanning units. We believe our low level of complaints, justifies continued usage of this simple exposure schedule.

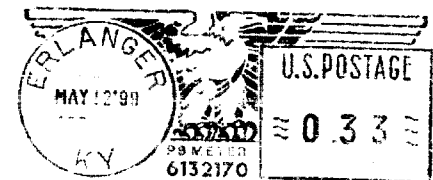
We also are in agreement with the Agency that suitable warning information needs to be provided the purchaser and user of tanning lamps. However, we are concerned about the proposed reproduction of warning text to appear in catalogues as being less effective than the possible inclusion of a simple UV hazard symbol as used throughout the lamp industry.

Respectively


James G. Shepherd
President
98N-1170

CT

SPERTI 
Manufactured by KBD Inc.
20 Kenton Lands Rd., Erlanger, Ky. 41018



Department of Health & Human Services
Dockets Management Branch (HFZ-305)
Food & Drug Administration
5630 Fishers Lane, Room 1061
Rockville, Md. 20852

20857-0001

